IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., ALLERGAN USA, INC., and ADAMAS PHARMA, LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MACLEODS PHARMACEUTICALS, LTD. and MACLEODS PHARMA USA, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., Allergan USA, Inc., and Adamas Pharma, LLC (collectively, "Plaintiffs"), for their Complaint against Defendants Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc. (collectively, "Macleods" or "Defendants"), hereby allege as follows.

PARTIES

1. Plaintiff Forest Laboratories, LLC is a Delaware limited liability company having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

2. Plaintiff Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Cumberland House, 1 Victoria Street, Hamilton HM11, Bermuda.

3. Plaintiff Allergan USA, Inc. is a Delaware corporation having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054 (referred to herein, together with Forest Laboratories, LLC and Forest Laboratories Holdings,

Ltd., as "Forest").

4. Plaintiff Adamas Pharma, LLC ("Adamas") is a Delaware limited liability company having a principal place of business at 1900 Powell Street, Suite 750, Emeryville, California 94608.

5. Upon information and belief, Macleods Pharmaceuticals, Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, India 400059. Upon information and belief, Macleods Pharmaceuticals, Ltd. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

6. Upon information and belief, Macleods Pharma USA, Inc. is a corporation organized under the laws of the State of Delaware, having its principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536.

7. Upon information and belief, Macleods Pharma USA, Inc. is the United States division, a wholly owned subsidiary, and alter ego of Macleods Pharmaceuticals, Ltd., and for purposes of this action, Macleods Pharma USA, Inc. and Macleods Pharmaceuticals, Ltd. are effectively the same entity.

NATURE OF THE ACTION

8. This is a civil action for the infringement of the following patents by Defendants: United States Patent Nos. 8,039,009 ("the '009 patent"), 8,168,209, as corrected ("the '209 patent"); 8,173,708 ("the '708 patent"); and, 8,283,379 ("the '379 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28

U.S.C. §§ 1331 and 1338(a).

10. This Court has specific personal jurisdiction over the Defendants by virtue of, *inter alia*, the fact that the Defendants intend to sell the proposed generic products at issue in this litigation in this judicial district upon receiving FDA approval. Furthermore, Defendants have committed, or aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in Delaware. This Court has personal jurisdiction over the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such personal jurisdiction is challenged.

11. This Court has personal jurisdiction over Defendant Macleods Pharmaceuticals, Ltd. by virtue of, *inter alia*: (1) its presence in Delaware, including through its agent Defendant Macleods Pharma USA, Inc.; and (2) its systematic and continuous contacts with Delaware, including through its agent Macleods Pharma USA, Inc. On information and belief, Macleods Pharmaceuticals, Ltd. is amenable to litigating in this forum based on Macleods Pharmaceuticals, Ltd.'s conduct in multiple prior litigations in this District. In particular, Macleods Pharmaceuticals, Ltd. did not contest jurisdiction in Civil Action No. 15-454 (D.I. 14) and Civil Action No. 15-464 (D.I. 14).

12. This Court has personal jurisdiction over Macleods Pharma USA, Inc. by virtue of, *inter alia*, the fact that Macleods Pharma USA, Inc. is a Delaware corporation.

13. Venue is proper in this judicial district as to both Defendants pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS

14. On October 18, 2011, the '009 patent, titled "Modified Release Formulations Of

Memantine Oral Dosage Forms," was duly and legally issued by the United States Patent and Trademark Office ("USPTO"). Since the issuance of the '009 patent, Forest Laboratories Holdings, Ltd. has been, and continues to be, the '009 patent's sole owner. A copy of the '009 patent is attached hereto as Exhibit A.

15. On May 1, 2012, the '209 patent, titled "Method And Composition For Administering An NMDA Receptor Antagonist To A Subject," was duly and legally issued by the USPTO. The USPTO issued a certificate of correction for the '209 patent on June 26, 2012. Adamas is the '209 patent's sole owner. Forest is the exclusive licensee of the '209 patent with respect to commercializing pharmaceutical products containing memantine in the United States. A copy of the '209 patent, including its certificate of correction, is attached hereto as Exhibit B.

16. On May 8, 2012, the '708 patent, titled "Method And Composition For Administering An NMDA Receptor Antagonist To A Subject," was duly and legally issued by the USPTO. Adamas is the '708 patent's sole owner. Forest is the exclusive licensee of the '708 patent with respect to commercializing pharmaceutical products containing memantine in the United States. A copy of the '708 patent is attached hereto as Exhibit C.

17. On October 9, 2012, the '379 patent, titled "Method And Compositions For The Treatment Of CNS-Related Conditions," was duly and legally issued by the USPTO. Adamas is the '379 patent's sole owner. Forest is the exclusive licensee of the '379 patent with respect to commercializing pharmaceutical products containing memantine in the United States. A copy of the '379 patent is attached hereto as Exhibit D.

18. Forest Laboratories, LLC holds New Drug Application ("NDA") 22-525 for Namenda XR® brand memantine hydrochloride extended release capsules. The '009 patent, the '209 patent, the '708 patent, and the '379 patent are listed in *Approved Drug Products with*

Therapeutic Equivalence Evaluations ("the Orange Book") for Namenda XR®.

19. Namenda XR® is manufactured by Forest Laboratories Ireland Ltd. for subsequent sale in the United States.

20. Allergan USA, Inc. is the exclusive distributor of Namenda XR® in the United States.

ACTS GIVING RISE TO THIS ACTION

Claim for Relief – Patent Infringement by Macleods

21. Upon information and belief, on or before April 19, 2017, Macleods submitted ANDA No. 206310 to the United States Food and Drug Administration ("FDA") under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 206310 seeks FDA approval for the commercial manufacture, use, and sale of generic extended release tablet products containing 7, 14, 21, and 28 milligrams of memantine hydrochloride as the active ingredient ("the Macleods Generic Products"). ANDA No. 206310 specifically seeks FDA approval to market the Macleods Generic Products prior to the expiration of '009 patent, the '209 patent, the '708 patent, and the '379 patent.

22. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 206310 alleges, *inter alia*, that the claims of '009 patent, the '209 patent, the '708 patent, and the '379 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Macleod Generic Products. None of the Plaintiffs received written notification of ANDA No. 206310 and its § 505(j)(2)(A)(vii)(IV) allegations earlier than April 21, 2017. The written notification, however, does not meet the requirements for notice set forth in 21 C.F.R. 314.95(c).

23. Macleods's submission of ANDA No. 206310 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of at least Claims 1, 2, and 21-23 of the '009 patent, Claims 1-4, 6, and 10-14 of the '209 patent, Claims 1, 3-5, and 6-9 of the '708 patent, and Claims 1-3 and 5 of the '379 patent, under 35 U.S.C. § 271(e)(2)(A). Moreover, if Macleods commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Macleods Generic Products, or induces or contributes to any such conduct, it would further infringe these claims of the '009 patent, the '209 patent, the '708 patent, and the '379 patent under 35 U.S.C. § 271(a), (b), and/or (c).

24. Macleods has infringed these claims under 35 U.S.C. § 271(e)(2)(A), and will further infringe these claims under 35 U.S.C. § 271(a), (b), and/or (c), because, *inter alia*, the Macleods Generic Products and the methods of using the Macleods Generic Products, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert will meet each and every claim element of one or more of Claims 1, 2, and 21-23 of the '009 patent, Claims 1-4, 6, and 10-14 of the '209 patent, Claims 1, 3-5, and 6-9 of the '708 patent, and Claims 1-3 and 5 of the '379 patent, either literally or under the doctrine of equivalents.

25. Upon information and belief, each of Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc. has participated in, contributed to, aided, abetted, and/or induced infringement of the '009 patent, the '209 patent, the '708 patent, and the '379 patent in connection with the preparation and submission of ANDA No. 206310 to the FDA and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '009 patent, the '209 patent, the '708 patent, and the '379 patent once the Macleods Generic Products are manufactured, used, offered for sale, or sold in the United States, or imported into the United States. Each of Macleods

Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc. is jointly and severally liable for the infringement of the '009 patent, the '209 patent, the '708 patent, and the '379 patent.

26. Upon information and belief, Macleods has knowledge that if it were to receive approval from the FDA to market the products described in ANDA No. 206310 and made said products available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, during the proposed shelf life of the products before expiration of '009 patent, the '209 patent, the '708 patent, and the '379 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Macleods has knowledge of such infringing use and also knows that the products described in ANDA No. 206310 are not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather are especially made and/or adapted for use in the direct infringement of '009 patent, the '209 patent, the '708 patent, and the '379 patent.

27. Upon information and belief, Macleods was aware of the '009 patent, the '209 patent, the '708 patent, and the '379 patent prior to filing ANDA No. 206310, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents. Upon information and belief, the proposed label for the Macleods Generic Products will induce others, *e.g.*, doctors, pharmacists, healthcare providers and patients, to infringe '009 patent, the '209 patent, the '708 patent, and the '379 patent, and based on Macleods's § 505(j)(2)(A)(vii)(IV) allegations, Macleods possesses the specific intent to encourage others to infringe.

28. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

29. Plaintiffs will be irreparably harmed by Macleods infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Defendants have infringed '009 patent, the '209 patent, the '708 patent, and the '379 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 206310 shall not be earlier than the expiration date of the last to expire of '009 patent, the '209 patent, the '708 patent, and the '379 patent, including any extensions or exclusivities;

C. That Macleods Pharmaceuticals, Ltd., its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the Macleods Generic Products, and any other product that infringes or induces or contributes to the infringement of '009 patent, the '209 patent, the '708 patent, the '379 patent, prior to the expiration date of the last to expire of those patents, including any extensions or exclusivities;

D. That Macleods Pharma USA, Inc., its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the Macleods Generic Products, and any other product that infringes or induces or contributes to the infringement of '009 patent, the '209 patent, the '708 patent, or the '379 patent, prior to the expiration date of the last to expire of those patents, including any extensions or exclusivities;

E. That Plaintiffs be awarded monetary relief if Defendants commercially make, use,

offer for sale, or sell in the United States, or import into the United States, the Macleods Generic Products, or any other product that infringes or induces or contributes to the infringement of '009 patent, the '209 patent, the '708 patent, or the '379 patent, prior to the expiration of the last to expire of those patents, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

F. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur prosecuting this action under 35 U.S.C. § 285; and

G. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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